UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

February 9, 2004

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 71700-E / Nok Out
DP Barcode: D296918

To: Wanda Mitchell, (Acting) PM 32
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: Amazing Concept Technologies, Inc.

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Chlorine Dioxide	0.200
N–Alkyl benzyl ammonium chlorides	0.085
–Alkyl dimethyl benzyl ammonium chlorides	0.085
Other Ingredient(s):	99.630
Total:	100%

BACKGROUND: Amazing Concepts, LLC, has submitted a complete "six-pack" of acute toxicity studies to support the registration of their new product, "Amazing Nok Out Odor Eliminator". The studies were conducted by MB Research Laboratories. The MRID Numbers are 461188-01 through 461188-06.

RECOMMENDATIONS: PSB findings are:

Each of the six studies is acceptable.

The acute toxicity profile for File Symbol 71700-E is currently:

acute oral toxicity	IV	Acceptable
acute dermal toxicity	IV	Acceptable
acute inhalation toxicity	IV	Acceptable
primary eye irritation	IV	Acceptable
primary skin irritation	IV	Acceptable
dermal sensitization	Nonsensitizer	Acceptable

LABELING:

1. The signal word is "CAUTION".

2. There are no requirements for precautionary statements for this product.

3. There are no requirements for first aid statements for this product.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1, 870.1100)

Product Manager: 32 **Reviewer**: I. Blackwell
MRID No.: 461188-01 **Study Completion Date**: 6/15/03
Lab Study No.: MB 03-10973.01
Testing Laboratory : MB Research Laboratories
Authors : Daniel R. Cerven

Quality Assurance (40 CFR §160.12): Included

Test Material: Nok Out, Lot Batch #100-70A; "clear liquid"

Species: Wistar albino rats
Age: 7-8 weeks
Weight: 181-189 grams
Source: Ace Animals

Conclusion:

1. **LD_{50} (mg/kg):** **Males =** (not determined)
   Females > 5,000
   Combined = (not determined)
2. **The estimated LD_{50} is greater than 5,000 mg/kg.**
3. **Tox. Category**: IV **Classification**: Acceptable

Procedure (Deviations from §81-1):
☞This study was conducted using the "Up and Down Method".
☞Only females were used in this study.

Results:

Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	Females	Combined
5,000	n/a	0/3	n/a

Observations: No abnormalities observed.

Gross Necropsy: No abnormalities observed.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2, 870.1200)

Product Manager: 32 **Reviewer**: Ian Blackwell
MRID No.: 461188-02 **Study Completion Date**: 7/15/03
Lab Study No.: MB 03-10973.02

Testing Laboratory: MB Research Laboratories
Author: Daniel R. Cerven

Quality Assurance (40 CFR §160.12): Included

Test Material: Nok Out, Lot Batch #100-70A; "clear liquid"

Species: New Zealand White rabbit
Weight: 2.6-3.0 kg **Age**: Approx. 16 weeks
Source: Millbrook Breeding Labs

Summary:

1. **LD_{50} (mg/kg)**: **Males** > 5,000 mg/kg
   Females > 5,000 mg/kg
   Combined > 5,000 mg/kg

2. **The estimated LD_{50} is greater than 5,000 mg/kg.**

3. **Tox. Category**: IV **Classification**: Acceptable

Procedure (Deviation From §81-2): none

Results:

Reported Mortality

DOSAGE (mg/kg)	**(NUMBER DEATHS/NUMBER TESTED)**		
	Males	**Females**	**Combined**
5,000	0/5	0/5	0/10

Observations: Flaking skin

Gross Necropsy Findings: No abnormalities were observed.

DATA REVIEW FOR ACUTE INHALATION TOXICITY (§81-3, 870.1300)

Product Manager: 32 **Reviewer:** I. Blackwell
MRID No.: 461188-05 **Study Completion Date**: 7/15/03
Report No.: MB 03-10973.05

Testing Laboratory: MB Research Laboratories
Author: Daniel R. Cerven

Quality Assurance (40 CFR §160.12): Included

Test Material: Nok Out, Lot Batch #100-70A; "clear liquid"
Concentration: 2.08 mg/L

Species: Wistar albino rats
Weight: males = 287-314 g; females = 186-226 g
Age: 8 weeks
Source: Ace Animals, Inc.

Summary:

1. **LC_{50} (mg/L):** **Males** > 2.08 mg/L
   Females > 2.08 mg/L
   Combined > 2.08 mg/L

2. **The estimated LC_{50} is greater than 2.08 mg/L of air.**

3. **MMAD**: 2.53 µm

4. **Tox. Category**: IV **Classification**: Acceptable

Procedure (Deviation From §81-3): (none)

Results:

Reported Mortality

Exposure Concentration	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
2.08 mg/L	0/5	0/5	0/10

Chamber Atmosphere			
Dose Level	MMAD	GSD	particles < 4.7 µm
2.08 mg/L	2.53 µm	2.63 µm	79.80%

Chamber Environment	
Chamber Volume	57 liter
Airflow	25 lpm
Temperature	22.4-23.6 ° C
Relative Humidity	32-34%

Clinical Observations: Chromodacryorrhea, emaciation, anogenital wetness, hunched posture, unkempt appearance, dyspnea, few feces, sagging eyelids.

Gross Necropsy Findings: No abnormalities were noted.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: 32
MRID No.: 461188-04

Reviewer: Ian Blackwell
Study Completion Date: 7/15/03
Report No.: MB 03-10973.04

Testing Laboratory: MB Research Laboratories
Author(s): Daniel R. Cerven, M.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Nok Out, Lot Batch #100-70A; "clear liquid"
Dosage: 0.1 mL
Species: New Zealand White rabbit
Sex: 3 males
Weight: 3.0-3.1 kg
Age: Approx. 17 weeks
Source: Millbrook Breeding Labs

Summary:

1. **Toxicity Category**: IV

2. **Classification**: Acceptable

Procedure (Deviations From §81-4):

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Corneal Opacity	0/3	0/3	0/3	0/3	—	—	---	---
Iritis	0/3	0/3	0/3	0/3	—	—	—	---
Conjunctivae								
Redness	0/3	0/3	0/3	0/3	—	—	—	—
Chemosis	0/3	0/3	0/3	0/3	—	—	—	—
Discharge	0/3	0/3	0/3	0/3	—	—	---	---

--- = no observations at this point

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: 32 **Reviewer**: Ian Blackwell
MRID No.: 461188-03 **Study Completion Date**: 7/15/03
Report No.: MB 03-10973.03

Testing Laboratory: MB Research Laboratories
Author: Theresa Hoff, Study Director

Quality Assurance (40 CFR §160.12): Included

Test Material: Nok Out, Lot Batch #100-70A; "clear liquid"
Dosage: 0.5 mL

Species: New Zealand White rabbit
Age: Approx. 17 weeks
Sex: 3 males **Weight**: 3.1-3.4 kg
Source: Millbrook Breeding Labs

Summary:

1. **Toxicity Category**: IV

2. **Classification**: Acceptable

Procedure (Deviations From §81-5): None

Results: There was no erythema or edema at any observation point.

Special Comments: None

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)

Product Manager: 32 **Reviewer**: I. Blackwell
MRID No.: 461188-06 **Study Completion Date**: 7/21/03
Report No.: MB 03-10973.06
Testing Laboratory: MB Research Laboratories
Author: Debra A. Hall, LaTg, Study Director

Quality Assurance (40 CFR §160.12): Included

Test Material: Nok Out, Lot Batch #100-70A; "clear liquid"
Positive Control Material: DNCB

Species: Hartley albino guinea pig
Weight: males = 316-402 g; females = 290-358g
Age: Approx. 4 weeks.
Source: Elm Hill Breeding Labs

Method: Buehler Method

Summary:

1. **This Product is not a dermal sensitizer.**

2. **Classification**: Acceptable

Procedure (Deviation From §81-6):

Procedure: The test animals were induced with 0.4 mL of 100% test material once per week, for three weeks for a total of three induction treatments. Fourteen days after the last (3rd) induction treatment, the animals were challenged with 0.4 mL of 100% test material.

Results: No irritation was observed in any of the test material-induced animals during the induction or challenge phases of the study. No irritation was observed during challenge in any of the naive challenge animals.

For the positive control portion of the study, the animals were dosed/ treated in the same fashion as the test material-treated animals. Twenty-four hours after induction treatment with 0.4mL of 0.2% DNCB #1, 5/20 animals displayed faint, usually confluent erythema, 5/20 displayed very faint, usually non-confluent erythema, and 10/10 displayed no erythema. Twenty-four hours after induction treatment #2, 12/20 displayed moderate erythema, 4/20 displayed faint, usually confluent erythema and 2/20 displayed very faint, usually non-

confluent erythema. Twenty-four hours after induction treatment #3, 8/20 displayed moderate erythema, 7/20 animals displayed faint, usually confluent erythema, 4/20 very faint, usually non-confluent erythema, 19/20 brown treatment areas, and 6/10 yellow-stained areas.

The positive control animals were challenged with 0.4 mL of 0.1% DNCB. Twenty-four hours after challenge with 0.4 mL of 0.1% DNCB, 1/20 positive control animals displayed moderate erythema, 8/20 faint, usually confluent erythema, 4/20 displayed very faint, usually non-confluent erythema, 6/20 no erythema and 20/20 brown staining. At this same point of the study, 1/10 naive control animals challenged with 0.4 mL of 0.1% DNCB animals displayed displayed very faint, usually non-confluent erythema and 9/10 displayed no erythema.